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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/702,718	11/01/2000	Moon Jong Noh	55293.00003	9523

7590

02/13/2004

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EXAMINER

WILSON, MICHAEL C

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 02/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/702,718	Applicant(s) NOH ET AL	
	Examiner Michael C. Wilson	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2003 and 24 November 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-5 and 13-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-5 13-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11-24-03 has been entered.

The amendment filed 7-18-03 has been entered. Applicant's arguments filed therein have been fully considered but they are not persuasive. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Claims 2-5 and 13-15 remain pending and under consideration in the instant application.

Claim Rejections - 35 USC ' 112 - new matter

1. Claim 2 as newly amended is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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The limitation of transfecting cells with a viral vector (claim 2) is new matter. Support has not been provided and cannot be found.

Claim Rejections - 35 USC ' 112 - indefiniteness

2. Claims 2-5 and 13-15 as newly amended are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "said recombinant viral vector" in claim 2 lacks antecedent basis.

The term "transplantation" in claim 4 lacks antecedent basis.

The phrase "resulting in a population of transfected connective tissue cell" in claim 13 does not correlate to the scope of the beginning of the claim which requires transfecting chondrocytes.

The phrase "the transfected population of chondrocytes" in claim 13 lacks antecedent basis.

The phrase "said transfection" in claim 14 lacks antecedent basis.

Claim Rejections - 35 USC ' 103

The rejection of claims 2-5 and 13-15 under 35 U.S.C. 103(a) as being unpatentable over Naughton (US Patent 5,842,477, Dec. 1, 1998) in view of Ikeda (Sept. 1998, J. Rheumatol., Vol. 25, pg 1666-1673) and van Beuningen (Sept. 1998, Osteoarthritis and Cartilage, Vol. 6, pg 306-317) has been withdrawn.

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The claims are drawn to injecting a composition consisting of transfected chondrocytes into a joint space of a mammal such that expression of DNA encoding TGF- β 1 within the joint space occurs resulting in the generation of hyaline cartilage in the joint space. The closest prior art teaches administering a composition consisting of chondrocytes transfected with a vector encoding TGF- β 1, scaffolding and a pharmaceutically acceptable carrier into a joint space of a mammal such that expression of TGF- β 1 occurs within the joint space and results in the generation of hyaline cartilage in the joint space.

The claims are distinguished over the prior art of record because the claims use closed language to describe the composition used in the method as consisting only of transfected chondrocytes and a pharmaceutically acceptable solution; the claims exclude using compositions comprising transfected chondrocytes, a pharmaceutically acceptable solution and scaffolding as in the prior art of record.

Double Patenting

The rejection of claims 2-5 and 13-15 under 35 U.S.C. 101 as claiming the same invention as that of claims 1-22 of copending Application No. 09/707900 has been withdrawn in view of the terminal disclaimer filed 7-18-03 which has been entered and is proper.

Conclusion

No claim is allowed.

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Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at 571-272-0738.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on 571-272-0804.

The official fax number for this Group is (703) 872-9306.

Michael C. Wilson

A handwritten signature in black ink, consisting of a series of vertical, wavy lines followed by a horizontal stroke that curves to the right.

**MICHAEL WILSON
PRIMARY EXAMINER**